REMARKS

Claims 8-10, 21, 23-25, 27 and 28 are presently pending. All claims were rejected.

Rejection Under 35 U.S.C. §§ 101 and 112, First Paragraph

Claims 8-10, 21, 23-25 and 27 are rejected under 35 U.S.C. §§ 101 and 112, first paragraph as allegedly lacking either a credible, specific and substantial asserted utility or a well established utility. According to the Action, the instant specification does not disclose the biological role or significance of the novel IL-B30 protein. The Action asserts that the experimental data provided in the instant specification is not persuasive with regards to a specific utility because IL-B30 was not established as a specific marker for a specific cell type. The Action further asserts that a mere suggestion of a role in a broad physiological process as inflammation does not constitute an assertion of a specific, credible and substantial utility for IL-B30. The Action concludes that Wiekowski, *et al.* is not persuasive of a utility until it is discloses what role IL-B30 plays in various cellular and immunological responses *in vivo*. Applicant respectfully traverses this rejection.

1. The specification discloses multiple specific utilities, *i.e.*, biological roles, for the novel IL-B30 protein that are supported by evidence of record.

The specification discloses several biological roles for IL-B30. For example, IL-B30 is disclosed as a cytokine likely to play a role in various immunological diseases. At page 15, lines 8-12, the IL-B30 is described as potentially useful in the treatment of various immune disorders including chronic inflammation. IL-B30 protein is also described being useful in the treatment of conditions associated with abnormal physiology or development, including inflammatory conditions at page 40, lines 1-3, of the instant specification. *See also* page 40, lines 15-35. The specification discloses the modulation of various hematopoietic and lymphoid cells as a use for IL-B30. *See, e.g.*, page 40, lines 6-9. The specification further discloses IL-B30 as a cytokine that mediates cytokine synthesis by cells and induce proliferation. See page 40, lines 23-25. IL-

B30 is also described as useful as a modulator of medical conditions and diseases involving activation by macrophages and monocytes. *See* page 41, lines 5-14.

The specification supports the disclosed utilities for IL-B30 with actual experimental data. At page 55, lines 9-19, the specification discloses a high expression of IL-B30 in activated human macrophages, activated human Th1 cells, and activated human dendritic cells. The cells expressing no IL-B30 or a lower amount of IL-B30 are described at page 55, line 19 to page 56, line 22. This distinct pattern of expression is confirmed in the data generated in murine cells. The specification discloses high IL-B30 expression in activated murine macrophages and activated murine Th1 cells. See page 58, lines 22-29. Cells expressing no IL-B30 or a lower amount of IL-B30 are described at page 58, line 29 to page 59, line 10.

Applicant specifically asserts IL-B30 has a role in inflammation based on the experimental data disclosed in the application, a utility supported by after-filing publications already in evidence. At page 56, lines 23-24, the specification states "the distribution shows IL-B30 elevated in activated macrophages, suggesting a role in inflammation." Wiekowski confirms that the constitutive expression of IL-B30 elicits multi-organ inflammation. Wiekowski, *et al., J. Immunol.* 166: 7563-70 (2001). The IL-B30-induced inflammation is characterized by the classic indicators of inflammation - neutrophilia (page 7566), increased serum concentrations of the pro-inflammatory cytokines, TNF-α and IL-1 (page 7566), and expression of acute phase proteins (pages 7566-67). *See* Exhibits A and B (describing the hallmarks of inflammation). This striking ability to induce systemic inflammation is retained and transferred in hematopoietic cells. *See* page 7568. Therefore, Wiekowski confirms that the cellular expression of IL-B30 in cells such as macrophages, lymphocytes and dendritic cells is sufficient to induce systemic inflammation.

Applicant also asserts IL-B30 has a regulator or effector role in Th1 immune responses based on the IL-B30 expression profile disclosed in the specification, a utility supported by after-filing publications already in evidence. *See* page 56, lines 25-27. Oppmann confirms the asserted role of IL-B30 in eliciting IFN-γ production (*i.e.*, cytokine synthesis), a cytokine clearly

recognized by one of skill in the art as definitive of Th1 immune responses. Oppmann first shows the pattern of IL-B30 expression disclosed in the instant specification, namely high expression in activated macrophages, polarized Th1 cells, and activated hematopoietic dendritic cells. Oppmann also demonstrates that IL-B30, when dimerized with the p40 subunit of IL-12, elicits IFN-γ synthesis from PHA blasts and CD45RO+ (*i.e.*, memory) T cells. Notably, Oppmann also demonstrates IL-B30 induces proliferation (*e.g.*, in human CD45RO+ T cells and murine $CD45RB^{lo}$ T cells), another utility disclosed by Applicant. *See* Specification at page 40, lines 23-25.

In sum, a person of ordinary skill in the art would immediately appreciate that IL-B30 has a role in inducing cytokine synthesis and proliferation and a role in immunological diseases, such as inflammation, based on the instant disclosure. Moreover, these utilities are fully supported by the evidence of record.

2. The utility of IL-B30 is specific and substantial.

Applicant respectfully submits that the specification sets forth at least one specific and substantial utility, thereby satisfying the utility requirement of 35 U.S.C. §§ 101 and 112. For example, the specification discloses IL-B30 is involved in inflammation, a specific and substantial utility. Contrary to the assertion of the Office, inflammation is a specific and discrete physiologic response that fulfills the criteria of specific, credible, and substantial. Inflammation describes a complex, but predictable response that includes defined cytokines (*e.g.*, IL-1, TNF-α), cellular components (*e.g.*, neutrophils, lymphocytes, macrophages), and other soluble mediators (*e.g.*, platelets) that interact to induce vascular permeability, cellular extravasation into tissue, and activation of the tissue-recruited cells. (*See, e.g.,* Exhibit A, at page 36-37, Exhibit B, at page 1051-52.) The diversity of the resulting disease states is specific to the organ system in which the inflammation occurs, not the initiating inflammatory process. The cascade of events described as "inflammation" is defined and well known as a biological process with common characteristics regardless of the organ system in which inflammation occurs. Therefore, Applicant asserts that inflammation qualifies as a specific and substantial process.

3. The utility of IL-B30 is credible.

Applicant discloses specific and substantial utilities for IL-B30 that would be believable to a skilled artisan. Based on the cellular expression of the IL-B30 in activated macrophages, polarized Th1 cells, and activated hematopoietic dendritic cells, Applicant discloses a utility for IL-B30 as having a role in inflammation and immunological responses. The evidence of record overwhelmingly supports the credibility of this utility. Based on the homology to other helical cytokines, Applicant reasoned that IL-B30 induces cytokine synthesis and proliferation. The evidence of record demonstrates the credibility of this utility.

Finally, Applicant respectfully submits that the Office has previously found that the instant disclosure satisfies the utility requirement under 35 U.S.C. § 101 in the co-pending application, U.S. Application Serial No. 09/935,366.

In light of the above remarks, Applicant respectfully submits that the rejections under 35 U.S.C. §§ 101 and 112, first paragraph are overcome. Therefore, Applicant requests the withdrawal of the rejections.

Rejection Under 35 U.S.C. § 112, First Paragraph

Claim 28 is rejected under 35 U.S.C. § 112, first paragraph as allegedly being indefinite. The Action asserts that a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation in the same claim is considered indefinite. Applicant respectfully traverses this rejection.

Applicant respectfully submits that claim 28 does not include a broad range with a narrower range within the broad range in the same claim. Claim 27 recites the broad range of at least 17 contiguous nucleotides of SEQ ID NO:3, while claim 28 recites a narrower range of at least 25, 45, 55, or 60 contiguous nucleotides of SEQ ID NO:3. In other words, claim 28 includes alternative ranges (as indicated by the proposition "or") that are each narrower than the broad range of claim 27, from which claim 28 depends. Because broad and narrow ranges are

not recited in claim 28, claim 28 clearly sets forth the metes and bounds of the claimed invention, and thus is sufficiently definite to satisfy 35 U.S.C. § 112, second paragraph.

In light of the above remarks, Applicant respectfully submits that the rejection under 35 U.S.C. § 112, first paragraph, is overcome. Therefore, Applicant requests the withdrawal of the rejection.

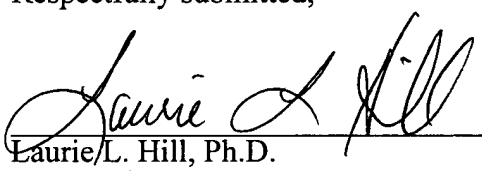
CONCLUSION

Applicant submits that the rejections under 35 U.S.C. §§ 101 and 112 have been overcome by the above remarks. Early allowance of pending claims 8-10, 21, 23-25, 27 and 28 is respectfully requested. If the Examiner feels that a telephonic conference would be helpful, please call the undersigned at 858-720-7955 at your convenience.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 140942000210.

Respectfully submitted,

Dated: February 27, 2003

By: 

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